CONTINUOUS EMISSIONS MONITORING SYSTEM
RELATIVE ACCURACY TEST AUDIT

Performed At
Pharmacia & Upjohn Company LLC
A subsidiary of Pfizer, Inc.
Thermal Oxidizer Unit 1 (TOX 1)
Kalamazoo, Michigan

Test Date(s)
July 19, 2023

Report No.
TRC Environmental Corporation Report 544843A

Report Submittal Date
September 11, 2023

TRC Environmental Corporation
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Lombard, Illinois 60148
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Report Certification

I certify that to the best of my knowledge:

- Testing data and all corresponding information have been checked for accuracy and completeness.
- Sampling and analysis have been conducted in accordance with the approved protocol and applicable reference methods (as applicable).
- All deviations, method modifications, or sampling and analytical anomalies are summarized in the appropriate report narrative(s).

Doug Ryan
AMS Midwest Regional Manager

September 11, 2023

Date

TRC was operating in conformance with the requirements of ASTM D7036-04 during this test program.

Bruce Randall
TRC Emission Testing Technical Director

TABLE OF CONTENTS

Appendix

CONTINUOUS EMISSIONS MONITORING SYSTEM
RELATIVE ACCURACY TEST AUDIT

1.0 INTRODUCTION

TRC Environmental Corporation (TRC) performed a continuous emissions monitoring system (CEMS) relative accuracy test audit (RATA) on July 19, 2023 on Thermal Oxidizer Unit 1 (TOX1) for Pfizer at Pharmacia & Upjohn Company, LLC in Kalamazoo, Michigan. The tests were authorized by and performed for Pharmacia & Upjohn Company, LLC.

The purpose of this test program was to evaluate the relative accuracy (RA) of the total organic compounds (TOC) CEMS on TOX1 stack while operating at >50% of normal load. Emission rates are expressed in terms of the applicable source standard(s). The test program was conducted according the TRC Test Protocol 544843, dated May 12, 2023.

1.1 Project Contact Information

Participants		
Test Facility	Pharmacia & Upjohn Company LLC A subsidiary of Pfizer, Inc. 7000 Portage Road Kalamazoo, Michigan 49001-0199 Permit No. MI-ROP-B3610-2021a State Registration No. B3610	Timothy Swainston Senior EHS Specialist - Environmental (269) 833-0080 (phone) timothy.swainston@pfizer.com
Air Emissions Testing Body (AETB)	TRC Environmental Corporation 207C Eisenhower Lane South Lombard, Illinois 60148	Greg Rock Field Team Leader (262) 960-3379 (phone) grock@trccompanies.com

The tests were conducted by Rome Rothgeb and Greg Rock of TRC. Documentation of the on-site ASTM D7036-04 Qualified Individual(s) (QI) can be located in the appendix to this report.

1.2 Facility and Process Description

The largest manufacturing site in the Pfizer network is located in Kalamazoo, Michigan. The 1,300-acre facility manufactures active pharmaceutical ingredients (API), drug products (DP) and medical devices.

Each year, the API facility in Kalamazoo produces 1,200 metric tons of ingredients through fermentation bioprocessing, custom ingredients synthesis and biologic antibody production. In addition, the DP organization ships 140 million units of life-saving medicine of both sterile injectables and liquid/semisolids. The facility also produces one medical device, which is used as a hemostat in surgery.

Pfizer operates two TOC CEMS (TOX1 and TOX2) at the Kalamazoo facility. An additional redundant TOC monitor has been configured in conjunction with the CEMS located on each primary thermal oxidizer stack. The redundant TOC CEMS is in service and can be used to collect data automatically in the event of a data quality or mechanical issue with the primary analyzer.

2.0 SUMMARY OF RESULTS

The table below presents a summary of the actual performance of the CEMS system, as compared to United States Environmental Protection Agency (USEPA) 40 CFR Part 60 specifications.

Load	Parameter	Reporting Unit	Performance Specifications (40CFR60)		CEMS Performance Relative Accuracy (%)
			Specification No.	Acceptance Criteria	
> 50%	TOC	ppmv as CH_4	8	RA ≤ 20% of applicable standard of 20 ppmvw*	3.90

*Pfizer Kalamazoo has obtained approval for use of an alternate relative accuracy requirement as detailed below:

As long as the TOC concentrations as measured by the Reference Method (RM) FIA remain below 50% of the 20 ppmc C_1 standard during the RATA, then Pfizer Kalamazoo regional control system TOC CEMS, the allowed relative accuracy will be 20% of the standard or 4 ppmv C_1. If the TOC concentrations as measured by the RM FIA are above 50% of the 20 ppmv C_1 standard, then the RA reverts back to the PS-8 criteria, or 10% of the standard.

3.0 DISCUSSION OF RESULTS

The complete test results from this program are presented in Section 6.0.

The data acquisition and handling system (DAHS) computer printout for the same time periods as the RM testing was used to determine the relative accuracy. The watches of the test crew were synchronized with the CEMS prior to testing.

No problems were encountered with the testing equipment during the course of the test program. Source operation appeared normal during the entire test program and operated at more than 50 percent of normal load. The daily average process gas flow to TOX1 or TOX2 for August 2022 through July 2023 was 2,066 scfm. The CEMS operation appeared normal with no apparent problems during sampling. No changes or problems were encountered that required modification of any procedures presented in the test plan. No adverse test or environmental conditions were encountered during the conduct of this test program. Operating data was recorded by plant personnel and is appended to this report.

4.0 TEST PROCEDURES

All testing, sampling, analytical, and calibration procedures used for this test program were performed in accordance with the methods presented in the following sections. Where applicable, the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume III, Stationary Source Specific Methods, USEPA 600/R-94/038c, September 1994 was used to supplement procedures.

4.1 Total Organic Concentration Determination by USEPA Method 25A

This method is applicable for the determination of total gaseous organic concentration of vapors consisting primarily of alkanes, alkenes, and/or arenes (aromatic hydrocarbons). The concentration is expressed in terms of methane.

A gas sample was extracted from the source through a heated sample line and glass fiber filter to a flame ionization analyzer (FIA). If necessary, a source-specific response factor was developed for the FIA.

5.0 QUALITY ASSURANCE PROCEDURES

TRC integrates our Quality Management System (QMS) into every aspect of our testing service. We follow the procedures specified in current published versions of the test Method(s) referenced in this report. Any modifications or deviations are specifically identified in the body of the report. We routinely participate in independent, third-party audits of our activities, and maintain:

- Accreditation from the Louisiana Environmental Laboratory Accreditation Program (LELAP).
- Accreditation from the Stack Testing Accreditation Council (STAC) and the American Association for Laboratory Accreditation (A2LA) that our operations conform with the requirements of ASTM D 7036 as an Air Emission Testing Body (AETB).

These accreditations demonstrate that our systems for training, equipment maintenance and calibration, document control and project management will fully ensure that project objectives are achieved in a timely and efficient manner with a strict commitment to quality.

All calibrations are performed in accordance with the test Method(s) identified in this report. If a Method allows for more than one calibration approach, or if approved alternatives are available, the calibration documentation in the appendices specifies which approach was used. All measurement devices are calibrated or verified at set intervals against standards traceable to the National Institute of Standards and Technology (NIST). NIST traceability information is available upon request.

ASTM D7036-04 specifies that: "AETBs shall have and shall apply procedures for estimating the uncertainty of measurement. Conformance with this section may be demonstrated by the use of approved test protocols for all tests. When such protocols are used, reference shall be made to published literature, when available, where estimates of uncertainty for test methods may be found." TRC conforms with this section by using approved test protocols for all tests.

6.0 TEST RESULTS SUMMARY

RATA Type: Total Hydrocarbon (THC), ppmvw as Methane
Regulation: 40CFR60, Appendix B, P.S. 8
Reference Method Used: 25A

		Plant Name:	Pfizer				Test Date:	7/19/2023	
		Unit:	TOX 1 Stack				Project Number:	544843	
		Monitor:	CAI 700-HFID				Serial Number:	2012013	
	Test Run	Date	Start Time	End Time	Reference Method THC ppmvw as Methane	CEM Output THC ppmvw as Methane	(RM-CEM) Difference (di)	Difference^2 (di^2)	
1	1	7/19/2023	7:10	7:30	1.57	0.97	0.60	0.360	
0	2	7/19/2023	7:41	8:01	1.41	0.55	0.86	0.740	
1	3	7/19/2023	8:11	8:31	1.35	0.56	0.79	0.624	
1	4	7/19/2023	8:44	9:04	1.29	0.57	0.72	0.518	
1	5	7/19/2023	9:19	9:39	1.26	0.45	0.81	0.656	
1	6	7/19/2023	9:50	10:10	1.26	0.48	0.78	0.608	
1	7	7/19/2023	10:21	10:41	1.05	0.37	0.68	0.462	
1	8	7/19/2023	10:54	11:14	1.17	0.48	0.69	0.476	
1	9	7/19/2023	11:26	11:46	1.04	0.38	0.66	0.436	
1	10	7/19/2023	11:58	12:18	1.10	0.31	0.79	0.624	

n		9
t(0.975)		2.306
Mean Ref. Method Value		1.232 RM
Mean CEM Value		0.508 CEM avg
Sum of Differences		6.520 di
Mean Difference		0.724 d avg
Sum of Differences Squared		4.765 di^2
Standard Deviation		0.072 sd
2.5% Error Conf.Coef(1-tail)		0.056 CC
RA based on AES:	20 ppmvw as Methane	3.90 %